AD_____

Award Number: DAMD17-01-1-0124

TITLE: Selenium and Breast Cancer Chemoprevention

PRINCIPAL INVESTIGATOR: Henry J. Thompson, Ph.D.

CONTRACTING ORGANIZATION: AMC Cancer Research Center
Lakewood, Colorado 80214

REPORT DATE: August 2002

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	August 2002	Annual (1 Aug 01 -31 Jul 02)

4. TITLE AND SUBTITLE
Selenium and Breast Cancer Chemoprevention

5. FUNDING NUMBERS
DAMD17-01-1-0124

6. AUTHOR(S):
Henry J. Thompson, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
AMC Cancer Research Center
Lakewood, Colorado 80214

E-MAIL:
thompsonh@amc.org

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT ***(Maximum 200 Words)***
The primary objective of this project is to determine whether selenium supplementation affects candidate markers of breast cancer risk in a cohort of women at elevated risk for breast cancer. The intermediate biomarkers to be studied are: indicators of oxidative damage to cellular macromolecules such as DNA and lipid, indicators of IGF metabolic status, and cellular indicators of breast cancer risk. We propose a randomized, placebo-controlled, double-blind chemoprevention trial with 150 participants (75 subjects per arm) using a placebo tablet or a tablet containing 200 µg high-selenium brewer's yeast per day, given for a duration of one year. The form and dose of selenium that will be used has been reported to reduce cancer incidence and mortality in lung, prostate, and colon. Blood and urine will be collected at baseline, and after 6 and 12 months of intervention. The feasibility of obtaining breast epithelial cells via nipple aspiration at baseline and the end of the intervention is being assessed. Plasma selenium and glutathione peroxidase activity will be evaluated in addition to pill counts and self report as markers of compliance.

14. SUBJECT TERMS:	15. NUMBER OF PAGES
breast cancer, prevention, chemoprevention, Selenium, oxidative damage, IGF-1	47
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

Table of Contents

Introduction

The primary objective of this project is to determine whether selenium supplementation affects candidate markers for breast cancer risk in a cohort of women at elevated risk for breast cancer. The intermediate biomarkers being studied are: indicators of oxidative damage to cellular macromolecules such as DNA and lipid, indicators of IGF metabolic status, and cellular indicators of breast cancer risk.

Body of Report

Approved Statement of Work

We are conducting a randomized, placebo-controlled, double-blind chemoprevention trial with 150 participants (75 subjects per arm) using a placebo tablet or a tablet containing 200 μg high-selenium brewer's yeast per day, given for a duration of one year. Blood and urine are being collected at baseline, and after 6 and 12 months of intervention. Efforts are being made to obtain breast epithelial and/or breast fluid via nipple aspiration using a modified breast pump. This procedure is performed at baseline and the end of the intervention. Randomization will be in 15 blocks of 10 subjects each.

1. Year 01
    a. Final development of project materials including Web-based randomization program, data entry screens, data quality assurance procedures, project databases.
    b. Obtain all supplements.
    c. Initiate recruitment and enter 3 blocks of 10 subjects.
    d. Schedule follow-up visits.
    e. Institute monthly patient follow-up.
    f. Ongoing collection and analyses of biological samples.
    g. Enter results into databases.
    h. Submit progress report.

2. Years 02-03

    a. Enter remaining subjects into the study and continue follow up, sample collection and analyses. Goal is 8 blocks of 10 in year 02 and 4 blocks of 10 in year 03.
    b. Submit progress reports.

3. Year 04

    a. Complete follow up and the collection and analysis of all samples.
    b. Evaluate all data.
    c. Summarize findings for publication and submit final report.

Acronym for Study We refer to this project as the **ENRICH** study.

Progress on Year 01 Objectives

a. Final development of project materials including Web-based randomization program, data entry screens, data quality assurance procedures, project databases.

This objective has been accomplished. We decided to develop a laptop computer based randomization process with daily backup to an FTP site that is monitored by the Data Coordinating Center staff. An extensive array of project materials were developed, reviewed and approved by the local and DOD IRB, and are in use. These materials are included in the appendix.

b. Obtain all supplements.

Placebo and selenium tablets were obtained from Cypress Systems Inc., Fresno, CA. The multi-vitamin and mineral supplement has the same formulation as being used in the NCI-sponsored SELECT trial and was obtained from BioAdventex Pharma, Wilmington, DE.

c. Initiate recruitment and enter 3 blocks of 10 subjects.
During this reporting period, recruitment was initiated and 27 individuals have been enrolled in the project.

d. Schedule follow-up visits. Follow-up visits are scheduled at the time of the baseline clinical visit. To date, this system is working effectively.

e. Institute monthly patient follow-up. Monthly calls are being placed to each individual participating in the project. These call are made by the project's clinical coordinator. The project nurse project follows-up if additional medical input is required. To date, this approach to compliance and safety monitoring has been well-received by participants and is working effectively.

f. Ongoing collection and analyses of biological samples. Upon collection, samples are immediately processed by the clinical coordinator. All samples are rapidly frozen when processing is completed, and are logged into the project database. Samples are evaluated per assay protocols.

g. Enter results into databases. As clinical and laboratory data are collected, they are entered into the project database. Hand entered data is either double-entered for validation or is 100% site-verified.

h. Submit progress report. This document.

Key Research Accomplishments All project materials (paper and electronic) required to initiate recruitment were completed during this reporting period, and enrollment in the project was initiated. Because of the double-blind study design, no biological data is currently available.

Reportable Outcomes (cumulative)

- Supporting intervention materials were developed and tested (when appropriate).
- The project database was completed
- Participants are being enrolled

Potential Obstacles The project's Nurse Practitioner was sent to both Fox Chase Cancer Center in Philadelphia, PA and the Breast Center at the University of Kansas which is directed by Dr. Carol Fabian for training in obtaining nipple aspirate fluid (NAF). To date, our success in obtaining adequate NAF samples is limited. To address this potential problem, two alternatives are being pursued. The PI has contacted staff at the Breast Center at UCSF in order to obtain additional training for the nurse practitioner. Also, the PI is establishing contacts with NCI collaborators to determine the feasibility of performing serum and/or nipple aspirate fluid-based proteomic analyses using SELDI-TOF as an alterative to cell-based risk assessment using NAF.

Conclusions Work is progressing as planned, and alternative approaches to cell-based risk assessment using NAF are being explored.

References (cumulative)

1. Clark,L.C., Combs,G.F., Jr., Turnbull,B.W., Slate,E.H., Chalker,D.K., Chow,J., Davis,L.S., Glover,R.A., Graham,G.F., Gross,E.G., Krongrad,A., Lesher,J.L., Jr., Park,H.K., Sanders,B.B., Jr., Smith,C.L., and Taylor,J.R. (1996) Effects of selenium supplementation for cancer prevention in patients with carcinoma of the skin. A randomized controlled trial. Nutritional Prevention of Cancer Study Group [see comments] [published erratum appears in JAMA 1997 May 21;277(19):1520]. *JAMA*, **276** , 1957-1963.

2. Clark,L.C., Combs,G.F., Jr., Turnbull,B.W., Slate,E.H., Chalker,D.K., Chow,J., Davis,L.S., Glover,R.A., Graham,G.F., Gross,E.G., Krongrad,A., Lesher,J.L., Jr., Park,H.K., Sanders,B.B., Jr., Smith,C.L., and Taylor,J.R. (1996) Effects of selenium supplementation for cancer prevention in patients with carcinoma of the skin. A randomized controlled trial. Nutritional Prevention of Cancer Study Group. *JAMA*, **276**, 1957-1963.
3. Clark,L.C., Dalkin,B., Krongrad,A., Combs,G.F., Jr., Turnbull,B.W., Slate,E.H., Witherington,R., Herlong,J.H., Janosko,E., Carpenter,D., Borosso,C., Falk,S., and Rounder,J. (1998) Decreased incidence of prostate cancer with selenium supplementation: results of a double-blind cancer prevention trial. *Br.J.Urol.*, **81**, 730-734.
4. Clark,L.C. and Marshall,J.R. (2001) Randomized, controlled chemoprevention trials in populations at very high risk for prostate cancer: Elevated prostate-specific antigen and high-grade prostatic intraepithelial neoplasia. *Urology*, **57**, 185-187.
5. Combs,G.F., Jr., Clark,L.C., and Turnbull,B.W. (1997) Reduction of cancer mortality and incidence by selenium supplementation. *Med.Klin.*, **92 Suppl 3**, 42-45.
6. Combs,G.F., Jr., Clark,L.C., and Turnbull,B.W. (1997) Reduction of cancer risk with an oral supplement of selenium. *Biomed.Environ.Sci.*, **10**, 227-234.
7. Nelson,M.A., Porterfield,B.W., Jacobs,E.T., and Clark,L.C. (1999) Selenium and prostate cancer prevention. *Semin.Urol.Oncol.*, **17**, 91-96.

Appendices

AMC CANCER RESEARCH CENTER FOR NUTRITION IN THE PREVENTION OF DISEASE
1600 Pierce Street • Denver, Colorado 80214 • www.amc.org

ENRICH

Information Sheet

Selenium and Breast Cancer Chemoprevention

Enrich Project

12-month study

Purpose of study

The purpose of this study is to determine whether selenium, taken as a tablet causes changes in early indicators of breast cancer risk. The study is being conducted in a group of women at increased risk for breast cancer. Past research indicates that the amount and type of selenium can reduce deaths due to cancer of the lung, prostate, and colon. However, the effects of selenium on breast cancer have not been studied. That is the purpose of this project.

The change from a normal breast cell into breast cancer takes many years and occurs in many stages. It is thought that breast cells destined to become cancer display changes that can be identified by laboratory tests before breast cancer occurs. Reversal of these changes by an agent such as selenium would suggest that we might be able to stop the cancer process. Due to selenium's antioxidant characteristics it may be possible to interrupt the chain of events that lead to breast cancer. The goal of this study is to determine whether taking selenium will decrease these cellular changes in the breast, blood, and urine, which may then help to decrease the risk of breast cancer.

Role of research subjects

- You will be asked to schedule three clinic visits; each visit is 6 months apart. At each visit you are asked to donate a sample of blood and to provide three first void urine specimens. At the first and last clinic visit, a sample of nipple aspirate fluid will also be obtained.
- You will be asked to take a selenium or placebo supplement along with a vitamin-mineral supplement on a daily basis for one year.
- You will be asked to update their BreastWatch questionnaire upon enrollment in the study, and again at the end of the study.

- You will be asked to discuss any questions or concerns with the Study Nurse Practitioner at any time. Also, you will be asked to update your health and pregnancy (if applicable) status at the monthly follow-up calls.

Costs of joining the study

- There are no costs to participate in this study apart from the costs associated with your annual clinical visit, and your annual routine breast examination and mammography.

ENRICH Selenium and Breast Cancer Chemoprevention

Participant Eligibility

- Participant must be female
- Must be at least 21 years old
- Must regularly consume 2 or fewer alcoholic beverages per day
- Must be willing to limit alcohol consumption to 1 or less serving of alcohol per day (a serving is defined as: 12 oz. beer or 5 oz. wine or 1 oz of hard liquor)
- Must refrain from using tobacco products
- Must not take a specific selenium supplement, for example a supplement with more than 50 mcg/day selenium.
- Must be willing to discontinue taking other vitamin-mineral supplements and take the vitamin-mineral supplement prescribed for everyone in the study
- Must not be pregnant or lactating
- Must not intend to become pregnant during the study

Whom do I contact if I am interested in participating?

Contact Becky Meinecke at (303) 242-3421 or (303) 336-5116 or email at meineckeb@amc.org

ENRICH

STUDY ID ☐☐☐☐

DATE ☐☐/☐☐/☐☐

CONTACT FORM

LAST NAME

FIRST NAME **MI**

ADDRESS

CITY **STATE** **ZIP CODE**

HOME PHONE ☐☐☐-☐☐☐-☐☐☐☐

WORK PHONE ☐☐☐-☐☐☐-☐☐☐☐ ext. ☐☐☐☐

SOCIAL SECURITY NUMBER ☐☐☐/☐☐/☐☐☐☐

DATE OF BIRTH ☐☐/☐☐/☐☐☐☐

Visit 1 Date ☐☐/☐☐/☐☐ **Appointment Time:** ☐☐:☐☐ O a.m. O p.m.

Visit 2 Date ☐☐/☐☐/☐☐ **Appointment Time:** ☐☐:☐☐ O a.m. O p.m.

Visit 3 Date ☐☐/☐☐/☐☐ **Appointment Time:** ☐☐:☐☐ O a.m. O p.m.

Visit 4 Date ☐☐/☐☐/☐☐ **Appointment Time:** ☐☐:☐☐ O a.m. O p.m.

For administrative purposes only:

ROSE ID

☐☐☐☐

ENRICH

STUDY ID ☐☐☐☐

ELIGIBILITY FORM

Inclusion Criteria:

Yes	No	
O	O	The subject must be female.
O	O	The subject must be 21 or older. May I have your date of birth? ☐☐/☐☐/☐☐ (1981)
O	O	Have you ever had a previous diagnosis of cancer (any type other than non-melanoma cancer)?

Exclusion Criteria:

Yes	No	
O	O	Do you regularly consume 2 or fewer alcoholic beverages per day?
O	O	Are you willing to limit alcohol consumption to one drink or less per day?
O	O	Do you use tobacco products?
O	O	To your knowledge, are you currently pregnant?
O	O	Are you planning on becoming pregnant in the next 12 months?
O	O	Are you currently breastfeeding?
O	O	Are you currently taking a multivitamin supplement
O	O	**If Yes**: Are you willing to stop taking your multivitamin supplement and take our standard daily multivitamin for the duration of the study? **If No:** Are you willing to take our standard daily multivitamin for the duration of the study?
O	O	Are you currently taking a selenium supplement
O	O	**If Yes:** Are you willing to stop taking your selenium supplement during the study? **If No:** Will you agree not to start a selenium supplement during the study?
O	O	Are you currently taking a vitamin E supplement?
O	O	**If Yes:** Are you willing to stop taking your vitamin E supplement during the study? **If No:** Will you agree not to start a vitamin E supplement during the study?
O	O	**If Eligible:** Have you filled out a BreastWatch Questionnaire? (if No, fill out Enrich Patient History Questionnaire, if yes, fill out update Questionnaire)
O	O	Subject is eligible for the study based in the inclusion and exclusion criteria. *A check in ANY shaded box means the subject is NOT eligible.*
O	O	Has informed consent been signed?

BreastWatch

STUDY ID

Welcome to BreastWatch, a special program for women at increased risk for breast cancer. An important part of this program is collecting detailed information about each participant. This information will help us to better understand risk factors and will provide valuable direction for ongoing research in breast cancer. All answers will be strictly confidential. Completing this questionnaire will require some time and may involve discussion with other family members. Please answer the following questions You may wish to ask family members for assistance.

NAME **DATE**

DATE OF BIRTH **SOCIAL SECURITY NUMBER**

ADDRESS

CITY **STATE** **ZIP CODE**

HOME PHONE

WORK PHONE

BreastWatch

STUDY ID

1. How did you hear about BreastWatch? (Please mark all that apply)
   - O Received a letter inviting my participation
   - O The program was recommended by friends/relatives
   - O My doctor suggested it
   - O I saw an ad in the newspaper
   - O Other; please specify:

2. **What is your marital status?**
   - O Single (never married)
   - O Married
   - O Divorced
   - O Separated
   - O Widowed

3. How do you describe yourself? Check all that apply.
   - O White
   - O African American/Black
   - O Hispanic/Latina
   - O Asian/Pacific Islander
   - O Aleutian/Eskimo, or American Indian
   - O Other; please specify:

4. **What is the highest level of education you have completed?**
   - O Elementary School (1 - 8 years)
   - O Some High School (9 - 11 years)
   - O High School Graduate (12 years)
   - O Some College, Associate Degree, Business or Technical (13-15 years)
   - O College Graduate (16 years)
   - O Post Graduate Training (17 + years)

5. What was your total household income last year from all sources before taxes?
   - O Under $9,999
   - O $10,000 - 19,999
   - O $20,000 - 29,999
   - O $30,000 - 39,999
   - O $40,000 - 49,999
   - O $50,000 - 59,999
   - O $60,000 - 69,999
   - O $70,000 - 79,999
   - O $80,000 or greater

10. When was your last physical exam or "regular check-up"?

Month Year
☐☐ / ☐☐☐☐

11. What type of health professional performed your last physical examination or "routine check-up"?

O General practitioner or physician/Family doctor
O General internist
O Gynecologist/obstetrician
O Nurse practitioner or physician assistant
O I don't have a doctor or health-care professional
O Don't know
O Other; please specify: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

12. Does this health professional also provide your other care for illnesses, accidents, etc.

O Yes O No

If no, who does?

O General practitioner/Family doctor
O Gynecologist/obstetrician
O General Internist
O Nurse practitioner or physician assistant
O I don't have a doctor or other health-care professional
O Don't know
O Other; please specify: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

13. How often do you perform breast self-examination to check for lumps or other changes?

O Never
O Not in the past year
O Only when I suspect something unusual or different
O 1-3 times a year
O 4-6 times a year
O 7-9 times a year
O 10-12 times a year
O More than 12 times in the past

14. When was the last time your breasts were examined physically by a health professional?

O Less than 1 year ago
O 1-2 years ago
O 2 or more years ago
O Never had this exam
O Not sure

15. When was the last time you had a mammogram? (An x-ray of your breasts to check for changes or suspicious areas in the breast tissue)

O Never had a mammogram
O Less than 1 year ago
O 1-2 years ago
O 2 or more years ago
O Not sure

16. Was your last mammogram performed for a problem or as a routine checkup?
O Routine checkup
O Breast problem

17. How old were you when you had your first menstrual period?
AGE ☐☐ O Don't know

18. Have you ever given birth?
O No O Yes
If yes, please specify:
☐☐ How many children have you given birth to, including stillborns but not miscarriages?
☐☐ How old were you when your first child was born?
☐☐ How old were you when your last child was born?

19. Have you ever breastfed a child?
O No O Yes
If yes, please estimate the number of total months you have breast-fed your children (all children added together):
Total months ☐☐☐

20. Are you still having menstrual periods?
O Yes
O Yes, but I am on estrogen replacement therapy
O Not sure
O No
If no, how old were you when you stopped having periods (either naturally or as a result of surgery)?
AGE
☐☐ O Not sure

21. Have you had any gynecologic (GYN) surgeries performed?
O No O Yes
If yes, please mark the following that apply
YEAR
O Hysterectomy (removal of your uterus) ☐☐☐☐
O Removal of one ovary ☐☐☐☐
O Removal of both ovaries ☐☐☐☐
O Other gynecologic surgery (please specify procedure and year) ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐

22. Have you ever been told you had any of the following conditions? O Yes O No
If no, skip to question #23. If Yes, please complete the following table.

	Yes	Age Diagnosed	No	Not Sure
Colon or rectal cancer	O	☐☐	O	O
Endometrial cancer (cancer of the uterus)	O	☐☐	O	O
Ovarian cancer	O	☐☐	O	O
Fibrocystic breast condition	O	☐☐	O	O
Breast cancer (If yes, please specify which breast)	*R* O	☐☐	O	O
	L O	☐☐	O	O
Other breast problem	O	☐☐	O	O
Other cancer ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	O	☐☐	O	O

23. Have any of your relatives been diagnosed with cancer? O No O Yes

If YES, please complete the following charts for the relative affected.
Table key: B = Breast, O = Ovarian, P = Prostate, C = Colon Y = Yes, N = No, NS = Not Sure

Relative	*Type of Cancer*				***Was she still having periods***			**Age Diag-nosed**	***Did (S)he die of cancer?***		
					Y	***N***	***NS***		Yes	No	NS
O Mother	O B	O O		O C	O	O	O	☐☐	O	O	O
O Father	O B		O P	O C				☐☐	O	O	O
O Sister #1	O B	O O		O C	O	O	O	☐☐	O	O	O
O Sister # 2	O B	O O		O C	O	O	O	☐☐	O	O	O
O Sister # 3	O B	O O		O C	O	O	O	☐☐	O	O	O
O Brother # 1	O B		O P	O C				☐☐	O	O	O
O Brother # 2	O B		O P	O C				☐☐	O	O	O
O Brother # 3	O B		O P	O C				☐☐	O	O	O
O Daughter # 1	O B	O O		O C	O	O	O	☐☐	O	O	O
O Daughter # 2	O B	O O		O C	O	O	O	☐☐	O	O	O
O Daughter # 3	O B	O O		O C	O	O	O	☐☐	O	O	O
O Son # 1	O B		O P	O C				☐☐	O	O	O
O Son # 2	O B		O P	O C				☐☐	O	O	O
O Son # 3	O B		O P	O C				☐☐	O	O	O

BreastWatch

STUDY ID ☐☐☐☐

Relative	Type of Cancer				Was she still having periods? Y	N	NS	Age Diagnosed	*Did (S)he die of cancer?* Yes	No	NS
Maternal Relatives (Mother's family)											
O Grandmother	O B	O O		O C	O	O	O	☐☐	O	O	O
O Grandfather	O B		O P	O C				☐☐	O	O	O
O Aunt	O B	O O		O C	O	O	O	☐☐	O	O	O
O Uncle	O B		O P	O C				☐☐	O	O	O
O Female Cousin	O B	O O		O C	O	O	O	☐☐	O	O	O
O Male Cousin	O B		O P	O C				☐☐	O	O	O
O Other ☐☐☐☐☐☐☐☐☐☐☐☐☐☐											
Paternal Relatives (Father's family)											
O Grandmother	O B	O O		O C	O	O	O	☐☐	O	O	O
O Grandfather	O B		O P	O C				☐☐	O	O	O
O Aunt	O B	O O		O C	O	O	O	☐☐	O	O	O
O Uncle	O B		O P	O C				☐☐	O	O	O
O Female Cousin	O B	O O		O C	O	O	O	☐☐	O	O	O
O Male Cousin	O B		O P	O C				☐☐	O	O	O
O Other ☐☐☐☐☐☐☐☐☐☐☐☐☐☐											

24. Have you ever had a breast cyst aspirated? (The insertion of a needle into your breast to remove some *fluid*)

O No O Not sure O Yes

If yes, please specify

O Left breast How many times? ☐☐

O Right breast How many times? ☐☐

25. Have you ever had a breast biopsy? (A small incision or insertion of a needle into your breast to remove some *tissue*)

O No O Not sure O Yes

If yes, please specify

O Left breast How many times? ☐☐

O Right breast How many times? ☐☐

BreastWatch

STUDY ID ☐☐☐☐

26. If possible, please list the date of each biopsy, the doctor who performed the procedure and his/her address, and the results.

1st biopsy DATE ☐☐/☐☐/☐☐ **RESULTS** O Benign (Non-cancerous) O Malignant (cancerous)

DOCTOR ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

ADDRESS ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

CITY ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ **STATE** ☐☐ **ZIP** ☐☐☐☐☐

2nd biopsy DATE ☐☐/☐☐/☐☐ **RESULTS** O Benign (Non-cancerous) O Malignant (cancerous)

DOCTOR ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

ADDRESS ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

CITY ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ **STATE** ☐☐ **ZIP** ☐☐☐☐☐

3rd biopsy DATE ☐☐/☐☐/☐☐ **RESULTS** O Benign (Non-cancerous) O Malignant (cancerous)

DOCTOR ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

ADDRESS ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

CITY ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ STATE ☐☐ ZIP ☐☐☐☐☐

4th biopsy DATE ☐☐/☐☐/☐☐ **RESULTS** O Benign (Non-cancerous) O Malignant (cancerous)

DOCTOR ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

ADDRESS ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

CITY ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ STATE ☐☐ ZIP ☐☐☐☐☐

BreastWatch

STUDY ID ☐☐☐☐

27. Have you ever been told your biopsy was not cancerous (negative or benign) but showed breast changes which require close observation or more frequent check-ups?
O Yes O No O Not sure

28. Have you had any other breast surgeries performed?

O No O Yes
If yes, please mark the following that apply
O Breast implants YEAR ☐☐☐☐
O Breast reduction YEAR ☐☐☐☐
O Other breast surgery (please specify procedure and year, but do not include biopsies)
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ YEAR ☐☐☐☐

29. Compared to other women your age, would you say your level of physical activity is (check one):

1 Sedentar y	2 Light Walkin g	3 Moderate 30min/day, 3 times/week	4 Active 1 hr/day 5 times/week	5 Very Active 2 hrs/day 5 times /week	6 Heavy Weight Training Twice/day 5 days/week
O	O	O	O	O	O

30. Have you ever smoked?
O Yes O No O Not sure

If you smoke now:

How old were you when you started to smoke? AGE ☐☐ O Not sure

On average, how many cigarettes do you smoke per day? NUMBER ☐☐ O Not sure

If you have smoked in the past but have quit,

How old were you when you started to smoke? AGE ☐☐ O Not sure

On average, how many cigarettes did you smoke per day? NUMBER ☐☐ O Not sure

How old were you when you quit? AGE ☐☐ O Not sure

31. A serving of fruits or vegetables is defined as :
    - a medium size apple
    - cup of chopped vegetables or fruit
    - 6 ounces of fruit juice

    About how many servings of fruits and vegetables do you usually eat or drink in an *average day*? Please include both fruit, vegetables, and juice in your number.

    # servings in an *average day*: ☐☐

32. What concerns would you like to discuss with us regarding breast cancer?

    _____

    _____

    _____

    _____

    _____

    _____

33. What do you believe your personal risk for breast cancer is?
    - O Very high
    - O High
    - O Average
    - O Low
    - O Very low

Appendix

BreastWatch Update

STUDY ID

NAME

DATE

DATE OF BIRTH

SOCIAL SECURITY NUMBER

ADDRESS

CITY

STATE

ZIP CODE

HOME PHONE

WORK PHONE

BreastWatch Update

STUDY ID

☐☐☐☐

2. **What is your marital status?**

O Single (never married)
O Married
O Divorced
O Separated
O Widowed

4. **What is the highest level of education you have completed?**

O Elementary School (1 - 8 years)
O Some High School (9 - 11 years)
O High School Graduate (12 years)
O Some College, Associate Degree, Business or Technical (13-15 years)
O College Graduate (16 years)
O Post Graduate Training (17 + years)

8. Compared to other women your age, would you say your health is ...

O Excellent
O Good
O Fair
O Poor

9. Compared to a year ago, would you say your health is ...

O Better
O About the same
O Worse

13. How often do you perform breast self-examination to check for lumps or other changes?

O Never
O Not in the past year
O Only when I suspect something unusual or
O 1-3 times a year
O 4-6 times a year
O 7-9 times a year
O 10-12 times a year
O More than 12 times in the past year

20. Are you still having menstrual periods?

O Yes
O Yes, but I am on estrogen replacement therapy
O Not sure
O No

If no, how old were you when you stopped having periods (either naturally or as a result of surgery)?

AGE

☐☐ O Not sure

BreastWatch Update

STUDY ID

21. Have you had any gynecologic (GYN) surgeries performed in the past year?

O No O Yes

If yes, please mark the following that apply

O Hysterectomy (removal of your uterus)
O Removal of one ovary
O Removal of both ovaries
O Other gynecologic surgery (please specify procedure and year)

22. Have you been told you had any of the following conditions in the past year? O Yes O No

If no, go to question #9. If Yes, please complete the following table.

	Yes	Age Diagnosed	No	Not Sure
O Colon or rectal cancer	O		O	O
O Endometrial cancer (cancer of the uterus)	O		O	O
O Ovarian cancer	O		O	O
O Fibrocystic breast condition	O		O	O
O Breast cancer (If yes, please specify which breast)	*R* O		O	O
	L O		O	O
O Other breast problem	O		O	O
O Other cancer	O		O	O

9. In the past year, have any of your relatives been diagnosed with cancer

O No O Yes

If YES, please complete the following chart for the relative affected.

Table key: B = Breast, O = Ovarian, P = Prostate, C = Colon Y = Yes, N = No, NS = Not Sure

Relative	*Type of Cancer*				***Was she still having periods***			***Age Diagnosed***	***Did (S)he die of cancer?***		
					Y	***N***	***NS***		Yes	No	NS
O Mother	O B	O O		O C	O	O	O		O	O	O
O Father	O B		O P	O C					O	O	O
O Sister #1	O B	O O		O C	O	O	O		O	O	O
O Sister # 2	O B	O O		O C	O	O	O		O	O	O
O Sister # 3	O B	O O		O C	O	O	O		O	O	O
O Brother # 1	O B		O P	O C					O	O	O

BreastWatch Update

STUDY ID

Relative	Type of Cancer				Was she still having periods? Y	N	NS	Age Diagnosed	*Did (S)he die of cancer?* Yes	No	NS
O Brother # 2	O B		O P	O C					O	O	O
O Brother # 3	O B		O P	O C					O	O	O
O Daughter # 1	O B	O O		O C	O	O	O		O	O	O
O Daughter # 2	O B	O O		O C	O	O	O		O	O	O
O Daughter # 3	O B	O O		O C	O	O	O		O	O	O
O Son # 1	O B		O P	O C					O	O	O
O Son # 2	O B		O P	O C					O	O	O
O Son # 3	O B		O P	O C					O	O	O
Maternal Relatives (Mother's family)											
O Grandmother	O B	O O		O C	O	O	O		O	O	O
O Grandfather	O B		O P	O C					O	O	O
O Aunt	O B	O O		O C	O	O	O		O	O	O
O Uncle	O B		O P	O C					O	O	O
O Female Cousin	O B	O O		O C	O	O	O		O	O	O
O Male Cousin	O B		O P	O C					O	O	O
Paternal Relatives (Father's family)											
O Grandmother	O B	O O		O C	O	O	O		O	O	O
O Grandfather	O B		O P	O C					O	O	O
O Aunt	O B	O O		O C	O	O	O		O	O	O
O Uncle	O B		O P	O C					O	O	O
O Female Cousin	O B	O O		O C	O	O	O		O	O	O
O Male Cousin	O B		O P	O C					O	O	O
O Other											

BreastWatch Update

STUDY ID ☐☐☐☐

Have you had a breast cyst aspirated in the past year? (The insertion of a needle into your breast to remove some *fluid*)

O No O Not sure O Yes

If yes, please specify

O Left breast How many times? ☐☐

O Right breast How many times? ☐☐

Have you had a breast biopsy in the past year (A small incision or insertion of a needle into your breast to remove some *tissue*)

O No O Not sure O Yes

If yes, please specify

O Left breast How many times? ☐☐

O Right breast How many times? ☐☐

12. If possible, please list the date of each biopsy, the doctor who performed the procedure and his/her address, and the results.

1st biopsy DATE ☐☐/☐☐/☐☐ RESULTS O Benign (Non-cancerous) O Malignant (cancerous)

DOCTOR ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

ADDRESS ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

CITY ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ STATE ☐☐ ZIP ☐☐☐☐☐

2nd biopsy DATE ☐☐/☐☐/☐☐ RESULTS O Benign (Non-cancerous) O Malignant (cancerous)

DOCTOR ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

ADDRESS ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

CITY ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ STATE ☐☐ ZIP ☐☐☐☐☐

27. Were you told your biopsy was not cancerous (negative or benign) but showed breast changes which require close observation or more frequent check-ups?

O Yes O No O Not sure

BreastWatch Update

STUDY ID ☐☐☐☐

13 Have you had any other breast surgeries performed in the past year?

O No O Yes

If yes, please mark the following that apply

O Breast implants YEAR ☐☐☐☐

O Breast reduction YEAR ☐☐☐☐

O Other breast surgery (please specify procedure and year, but do not include biopsies)

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ YEAR ☐☐☐☐

29. Compared to other women your age, would you say your level of physical activity is (check one):

1	2	3	4	5	6
Sedentary	Light	Moderate	Active	Very Active	Heavy Weight Training
	Walking	30min/day, 3 times/week	1 hr/day 5 times/week	2 hrs/day 5 times /week	Twice/day 5 days/week
O	O	O	O	O	O

30. Has your use of tobacco products changed in the last year?

O Yes O No O Not sure

If YES and you started to smoke:

How old were you when you started to smoke? AGE ☐☐

On average, how many cigarettes do you smoke per day? NUMBER ☐☐ O Not sure

If YES and you quit smoking:

How old were you when you started to smoke? AGE ☐☐

On average, how many cigarettes did you smoke per day? NUMBER ☐☐ O Not sure

How old were you when you quit? AGE ☐☐

31. A serving of fruits or vegetables is defined as :

- a medium size apple
- cup of chopped vegetables or fruit
- 6 ounces of fruit juice

About how many servings of fruits and vegetables do you usually eat or drink in an *average day*? Please include both fruit, vegetables, and juice in your number.

servings in an *average day*: ☐☐

BreastWatch Update

STUDY ID

33. What do you believe your personal risk for breast cancer is?
- O Very high
- O High
- O Average
- O Low
- O Very low

Appendix

ENRICH

STUDY ID

MEDICATIONS AND SUPPLEMENTS QUESTIONNAIRE

PRESCRIPTION MEDICATIONS

Please record any prescription medication you take.

Name of prescription medicine #1 :

Dose mg

Number of pills

O each day
O every other day
O as needed

Length of time on medication

O days O months O years

Reason for taking medication:

Name of prescription medicine #2 :

Dose mg

Number of pills

O each day
O every other day
O as needed

Length of time on medication

O days O months O years

Reason for taking medication:

Name of prescription medicine # 3:

Dose mg

Number of pills

O each day
O every other day
O as needed

Length of time on medication

O days O months O years

Reason for taking medication:

Name of prescription medicine #4:

Dose mg

Number of pills

O each day
O every other day
O as needed

Length of time on medication

O days O months O years

Reason for taking medication:

Name of prescription medicine # 5:

Dose mg

Number of pills

O each day
O every other day
O as needed

Length of time on medication

O days O months O years

Reason for taking medication:

Appendix

ENRICH

STUDY ID

OVER-THE-COUNTER (OTC) MEDICATIONS

Please record any OTC medication you take

Name of OTC medicine #1 : example *sudafed*

Dose mg

Number of pills

O each day
O every other day
O as needed

Length of time on medication

O days O months O years

Reason for taking medication: *example* cold and sinuses

Name of OTC medicine #2 :

Dose mg

Number of pills

O each day
O every other day
O as needed

Length of time on medication

O days O months O years

Reason for taking medication:

Name of OTC medicine # 3:

Dose mg

Number of pills

O each day
O every other day
O as needed

Length of time on medication

O days O months O years

Reason for taking medication:

Name of OTC medicine #4:

Dose mg

Number of pills

O each day
O every other day
O as needed

Length of time on medication

O days O months O years

Reason for taking medication:

Appendix

ENRICH

STUDY ID

MULTIVITAMIN

Name of Multivitamin:

Dose mg

Number of pills taken each day

Length of time on medication

O days O months O years

Reason for taking medication:

SUPPLEMENTS

Please record any vitamin, mineral, or other supplement you take. This would be in addition to or in place of the multivitamin/mineral supplement if previously specified.

Name of supplement # 1: example *zinc*

Dose O mg O mcg

Number of pills taken O daily O every other day O as needed

Length of time on medication

O days O months O years

Reason for taking supplement: example antioxidant

Name of supplement # 2:

Dose O mg O mcg

Number of pills taken O daily O every other day O as needed

Length of time on medication

O days O months O years

Reason for taking supplement:

Name of supplement # 3:

Dose O mg O mcg

Number of pills taken O daily O every other day O as needed

Length of time on medication

O days O months O years

Reason for taking medication:

Name of supplement # 4:

Dose O mg O mcg

Number of pills taken O daily O every other day O as needed

Length of time on medication

O days O months O years

Reason for taking supplement:

Name of supplement # 5:

Dose O mg O mcg

Number of pills taken O daily O every other day O as needed

Length of time on medication

O days O months O years

Reason for taking supplement:

Use this letter for individuals who do not schedule their visit 1 appointment for the same day as their BreastWatch visit.

AMC CANCER RESEARCH CENTER FOR NUTRITION IN THE PREVENTION OF DISEASE
1600 Pierce Street • Denver, Colorado 80214 • www.amc.org

ENRICH

Date

Name
Address
City State Zip

Dear Name:

I enjoyed talking with you recently about our ENRICH project. Our project team is delighted to know that you are interested in joining us in our research efforts to prevent and control the occurrence of breast cancer. We think that you will find our time together both challenging and rewarding. Through your efforts we hope to make progress toward important discoveries concerning nutrition and cancer prevention.

You are scheduled for your initial visit in Dr. Sedlacek's office on *date* at *time*. We expect this first visit to last between 90 minutes and 2 hours.

Enclosed with this letter is a brief description of ENRICH study and a copy of the Informed Consent document. We ask that you carefully read the Informed Consent documents. It contains critical information about your participation in our study. Please feel free to call me if you have any questions or concerns regarding this document. We will have time do discuss the Informed Consent on the day of your appointment.

We would also like to ask that you carefully fill out the medications and supplement forms we have included in your packet. It is very important for us to capture all medications and vitamin, mineral or herbal supplements that you are currently taking

If you have any questions, or should you need to re-schedule your appointment, please call me at (303) 336-5116. Once again, thank you for your interest. We look forward to seeing you.

Sincerely,

Becky Meinecke
ENRICH Clinical Coordinator

Enclosures

ENRICH

STUDY ID ☐☐☐☐

URINE COLLECTION INSTRUCTION SHEET

Enclosed are four plastic containers (one large container and three small containers) for collecting and storing urine samples prior to your clinic visit scheduled on

☐☐/☐☐/☐☐ at ☐☐:☐☐ O a.m. O p.m.

We ask you to collect your first urine void each morning on three consecutive days. Please carefully read the instructions for collection and storage of your urine samples. Please be sure to check your study calendar for the specific dates on which to collect your urine samples.

INSTRUCTIONS FOR COLLECTING AND STORING THE URINE SAMPLES:

- **Sample 1** **Date to be collected:** ☐☐/☐☐/☐☐

1. After you wake up in the morning, collect your first morning void into the large plastic container.
2. Next, transfer 3 ounces or 90 ml of urine from the large container into the smaller container labeled **Sample 1**. To prevent overflow due to expansion upon freezing, do not fill the smaller container to above the 3 ounce mark. Be sure to screw the lid back on **tightly** to prevent leakage.
3. After the lid is on securely, write the date you collected the sample on the label on the Sample 1 container.
4. Next, place the labeled container in your **freezer**. The sample needs to be stored frozen until you bring it to Dr. Sedlacek's office on the day of your clinic visit.

5. The large container should be rinsed and reused to collect Samples 2 and 3.

Sample 2 **Date to be collected:** ☐☐/☐☐/☐☐

Follow the same instructions you followed for Sample 1 above. Except this time transfer 3 ounces or 90 ml of urine from the large container labeled Sample 2. Don't forget to write the date of the collection on the label on the Sample 2 container.

Sample 3 **Date to be colleted:** ☐☐/☐☐/☐☐

Follow the same instructions you followed for Sample 1 above. Except this time transfer 3 ounces or 90 ml of urine from the large container labeled Sample 3. Don't forget to write the date of the collection on the label on the Sample 3 container.

Date of clinic visit: ☐☐/☐☐/☐☐

Today is your clinic visit for the ENRICH Project. Please bring all three frozen urine samples to your clinic visit. Be sure to place them in the purple bag provided. It is very important that the samples are protected from excessive heat and direct sunlight during the transport.

If you have any questions, please contact Becky Meinecke, Clinical Coordinator, at 303-336-5116.

YOUR PARTICIPATION IS GREATLY APPRECIATED.

Appendix

ENRICH

STUDY ID ☐☐☐☐

Physical Exam Form EXAM DATE ☐☐/☐☐/☐☐ **VISIT #** ☐ **GAIL SCORE** ☐☐

Height: ☐**ft** ☐☐**in.** **Weight:** ☐☐☐ **lbs.** **Blood Pressure:** ☐☐☐/☐☐☐ **Pulse:** ☐☐☐

BREAST EXAM

RIGHT:

- O Normal
- O Abnormal, no change from previous visit
- O Abnormal, new changes but not suspicious for malignancy
- O Abnormal, new changes suspicious for malignancy

COMMENTS: _____

LEFT:

- O Normal
- O Abnormal, no change from previous visit
- O Abnormal, new changes but not suspicious for malignancy
- O Abnormal, new changes suspicious for malignancy

COMMENTS: _____

MAMMOGRAM REVIEW

RIGHT:

DATE: ☐☐/☐☐/☐☐

DENSITY (1-10): ☐☐

RESULTS:

- O Normal
- O Abnormal, no change from previous visit
- O Abnormal, new changes but not suspicious for malignancy
- O Abnormal, new changes suspicious for malignancy

COMMENTS: _____

LEFT:

DATE: ☐☐/☐☐/☐☐

DENSITY (1-10): ☐☐

RESULTS:

- O Normal
- O Abnormal, no change from previous visit
- O Abnormal, new changes but not suspicious for malignancy
- O Abnormal, new changes suspicious for malignancy

COMMENTS: _____

PATHOLOGY REVIEW

RIGHT:

DATE: ☐☐/☐☐/☐☐

RESULTS:

- O No diagnostic features
- O Fibroadenoma
- O Fibrocystic Change
- O Hyperplasia/Sclerosing Adenosis
- O Atypical Hyperplasia
- O LCIS
- O DCIS
- O Cancer
- O Other (specify):

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

COMMENTS: _____

LEFT:

DATE: ☐☐/☐☐/☐☐

RESULTS:

- O No diagnostic features
- O Fibroadenoma
- O Fibrocystic Change
- O Hyperplasia/Sclerosing Adenosis
- O Atypical Hyperplasia
- O LCIS
- O DCIS
- O Cancer
- O Other (specify):

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

COMMENTS: _____

FOLLOWUP INFORMATION

- O Follow-up visit in : O 3 O 6 O 9 O 12 months (date: ☐☐/☐☐/☐☐)
- O Follow-up with primary care physician in six months & BREASTWATCH in one year.
- O Send letter in six months
- O Patient needs mammogram in O 3 O 6 O 9 O 12 months
- O Patient does not need mammogram in six months

ENRICH

STUDY ID ☐☐☐☐

RANDOMIZATION FORM

Date Randomization Completed ☐☐/☐☐/☐☐

Date Density Analysis Completed ☐☐/☐☐/☐☐

Breast Density ☐☐ Left ☐☐ Right

Gail Score ☐☐

Color Code Assignment
- O RED
- O GREEN
- O BLUE
- O BLACK

Appendix

ENRICH

STUDY ID ☐☐☐☐

Visit 1 Flowsheet

Date ☐☐/☐☐/☐☐

- Essential Forms:

Signed Consent form: ☐ Completed Eligibility form: ☐

Updated BreastWatch form: ☐ Medication/Supplement form: ☐

- Visit 1 Samples

Urine: ☐

Pregnancy test ☐Positive ☐Negative

Menstrual History: LMP: ☐☐/☐☐/☐☐

Cycle: ☐☐ days ☐ Irregular

Blood:

1-EDTA tube: ☐

2-Paxgene tubes: ☐

4- CPT tubes: ☐

1-EDTA tube: ☐

Time drawn: ☐☐:☐☐

Vital Signs:

Height: ☐ ft ☐☐ in

Weight: ☐☐☐ lbs

Blood Pressure: ☐☐☐/☐☐☐

Pulse: ☐☐☐

Nipple Aspirate Fluid: ☐ Yes ☐ No

Physical Exam: ☐☐/☐☐/☐☐

- Subject Handouts:

Pill Supply: ☐ Sample Containers/ Instruction sheets: ☐

Study Calendar: ☐ Appoint card: ☐

- Comments:

Visit 2 Date: ☐☐/☐☐/☐☐ Appointment Time: ☐☐:☐☐ O a.m. O p.m.

Appendix

ENRICH

STUDY ID ☐☐☐☐

Visit 2 Flowsheet

Date ☐☐/☐☐/☐☐

- Medical Screening:
  - **Medication and Supplement Questionnaire:** ☐
  - Physical Exam: ☐
  - Last month study tablets ☐
  - Last month multivitamins ☐

When do you usually take your study tablets?
O breakfast
O lunch
O dinner
O bedtime

- Visit 2 Samples

Urine: ☐☐☐ Visit one urine: ☐☐☐ Date urine received: ☐☐/☐☐/☐☐

Blood: ☐ Vital Signs: ☐

1-EDTA tube: ☐
2-Paxgene tubes: ☐
4- CPT tubes: ☐
1-EDTA tube: ☐
Time drawn: ☐☐:☐☐

Height: ☐☐.☐ in
Weight: ☐☐☐ lbs
Blood Pressure: ☐☐☐/☐☐☐
Pulse: ☐☐☐

- Subject Handouts:
  - **Pill Supply:** ☐
  - Study Calendar: ☐
  - Sample Containers/ Instruction sheets: ☐
- Comments:

Visit 3 Date: ☐☐/☐☐/☐☐ Appointment Time: ☐☐:☐☐ O a.m. O p.m.

Mammogram Ordered: ☐☐/☐☐/☐☐

Appendix

ENRICH

STUDY ID ☐☐☐☐

Date ☐☐/☐☐/☐☐

Visit 3 Flowsheet

- Medical Screening:

  Updated BreastWatch Questionnaire: ☐

  Medication and Supplement Questionnaire: ☐

  Mammogram: ☐

  Last month study tablets ☐

  Last month multivitamins ☐

When do you usually take your study tablets?

O breakfast
O lunch
O dinner
O bedtime

- Visit 3 Samples

  Urine: ☐ ☐ ☐

  Date Urine Received: ☐☐/☐☐/☐☐

  Blood: ☐

  1-EDTA tube: ☐

  2-Paxgene tubes: ☐

  4- CPT tubes: ☐

  1-EDTA tube: ☐

  Time drawn: ☐☐:☐☐

  Vital Signs: ☐

  Height: ☐☐.☐ in

  Weight: ☐☐☐ lbs.

  Blood Pressure: ☐☐☐/☐☐☐

  Pulse: ☐☐☐

  Nipple Aspirate Fluid ☐

- Comments:

ENRICH

STUDY ID

STUDY TABLET DISTRIBUTION & RECONCILIATION

Study Tablet Color Code: O Red O Green O Blue O Black

Study Tablet Bottle	Study Tablet ID Number	Date Issued	Date Returned	Quantity Dispensed	# of tablets prescribed	# of tablets left in bottle	# of tablets taken	% compliance
1		/ /	/ /	40				
2		/ /	/ /	40				
3		/ /	/ /	40				
4		/ /	/ /	40				
5		/ /	/ /	40				
6		/ /	/ /	40				
7		/ /	/ /	40				
8		/ /	/ /	40				
9		/ /	/ /	40				
10		/ /	/ /	40				
11		/ /	/ /	40				
12		/ /	/ /	40				
13		/ /	/ /	40				

MULTIVITAMIN DISTRIBUTION & RECONCILIATION

Multi-vitamin Tablet Bottle	Date Issued	Date Returned	Quantity Dispensed	# of tablets prescribed	# of tablets left in bottle	# of tablets taken	% compliance
1	/ /	/ /					
2	/ /	/ /					

ENRICH

STUDY ID
☐☐☐☐

Date
☐☐/☐☐/☐☐

Monthly Telephone Contact Form

- Health status:

Compared to a month ago, would you say your health is ...
O Better O **About the same** O **Worse**

Comments

- Reproductive Status (Only ask this question of women that reported that they are still menstruating naturally)

Do you have any reason to believe that you may be pregnant?
O Yes O **No**

- Compliance Status:

Are you taking your study tablet and multivitamin-mineral supplement daily?
O Yes O **No**

Are you experiencing any difficulty in taking your study tablet or multivitamin supplement?
O Yes O **No**

Have you returned your unused bottles of tablets for this month using the self-addressed mailer?

O Yes O **No**
Do you know the physical location (in your home) of the bottles of study tablets and multivitamin-mineral supplements that you will be using next month?

O Yes O **No**

- Comments:

ENRICH

STUDY ID ☐☐☐☐

Adverse Events

Date Reported ☐☐/☐☐☐/☐☐

Nipple Aspirate Fluid:

O Bruising

O Tenderness

O Other (please Specify): ☐

Blood Samples:

O Hematoma large

O Infection

O Other (please specify): ☐

Selenium:

O Nausea
O Anxiety
O Sweating
O Vomiting
O Skin Rash
O Depression
O Brittle hair
O Nail Changes
O Muscle weakness
O Liver abnormalities
O Garlic breath
O Other: ☐

Other unanticipated reactions: ☐

ENRICH

STUDY ID

STUDY WITHDRAWAL FORM

DATE OF WITHDRAWL

__/__/__

REASON FOR WITHDRAWAL:

O Unable to contact (3 phone call attempts)

O Withdrawal from study by participant

- O Inconvenience
- O Adverse Event
- O Illness
- O Other Reason:

O Withdrawal from study by physician (please choose one of the following):

- O Adverse Event
- O Illness
- O Diagnosed CANCER
- O Non-compliance
- O Other Reason:

O Average level of compliance is <70%

Irregular Sample Loglog

1600 Pierce Street • Denver, Colorado 80214 • www.amc.org
CENTER FOR NUTRITION IN THE PREVENTION OF DISEASE

ENRICH

To:

From:

Subject ID:

Date:

Clinical Comments:

To:

From:

Subject ID:

Date:

Laboratory Comments:

ENRICH DATA DICTIONARIES

ELIGIBILITY

Variable name	Type and size	Required	format	Comments/**label**
ENRICHID	I 4		F4.0	autofill **Enrich ID**
ENRDATE	Mmddyy10.		Mmddyy10.	Auto fill **Date Enrolled**
SEX		R	1=Female 0=Male	Default=1
OVER21	I4	R	1=Yes 0=No	**Over 21**
DOB		R	Mmddyy10.	
AGE				floor ((intck('month',DOB,TODAY()) - (day(TODAY()) < day(DOB))) / 12)
HxCA		R	1=Yes 0=No	**History of Cancer**
ALCOHOL		R	1=Yes 0=No	**Alcohol GT 2/day**
LMTALC		R	1=Yes 0=No	**Will Limit Alcohol**
TOBACCO		R	1=Yes 0=No	**Uses Tobacco**
PREGNANT		R	1=Yes 0=No	**Pregnant**
PLANPREG		R	1=Yes 0=No	**Plan Preg in 12 mon**
BRFEED		R	1=Yes 0=No	**Breast Feeding**
MULTI		R	1=Yes 0=No	**MultiVitamins**
STUDYSUPP		R	1=Yes 0=No	**Will Take Study MV**
SESUPP		R	1=Yes 0=No	**Se Supplement**
QTSESUPP		R	1=Yes 0=No	**Will Stop Se**
ESUPP		R	1=Yes 0=No	**Vit E Supplement**
QTESUPP		R	1=Yes 0=No	**Will Stop Vit E**
ELIGIBLE			1=Yes 0=No	Autofill: 1 If SEX=1 and age>=21 and HxCA=0 and ALCOHOL=0 and TOBACCO=0 and LMTALC=1 and PREGNANT=0 and BRFEED=0 and PLANPREG=0 and STUDYSUPP=1 and QTSESUPP=1 and QTESUPP=1 else 0
BWQ			1=Yes 0=No	If 1, go to KEYSEN and read LNAME

				lookup in KEYSBW and print selection of LNAMEs for choice; if no matching LNAME, assign next ID in sequence; update or add contact info. COPY TO KEYSEN. If 0, go to *add record* in KEYSEN and assign next ID in sequence (3001, ...); do not allow exit without LNAME, FNAME, and at least one of HPHONE, WPHONE **BreastWatch**
CONSENT			1=Yes 0=No	**Consent Signed**
VISIT1APP	Mmddyy10.		Mmddyy10.	**Appt Date V1**
V1APPTM	HH:MM		HH:MM	Integer fmt OK – will not be used in computations **Appt Time V1**
V1APPAMPM	$2		AM PM	**AMPM V1**

CONTACT (KEYSBW)

Variable name	Type and size	format	Comments/**label**
ROSEID	I 4	F4.0	Autofill (key field) **BreastWatch ID**
LNAME	$20		**Last Name**
FNAME	$20		**First Name**
MI	$1		**MI**
DOB	Num 8	DATETIME20	*Between 1917 and 1981* **Date of Birth**
ADDRESS	$40		**Address**
CITY	$20		**City**
STATE	$2		**State**
ZIP	ZIP	$5	**Exactly 5 digits** **Zip Code**
HOMEPHONE	PHONE#	$15	*Exactly 10 digits* **Home Phone**
WORKPHONE	PHONE #	$15	*Exactly 10 digits* **Work Phone**
SSN	SSN	$11	**Exactly 9 digits** **SSN**
CELL	PHONE#	$15	*Exactly 10 digits* **Cell Phone**
EMAIL	$20	$20	**Email Address**
DATE	Num 8	DATETIME20	*Earlier than TODAY()* **DATE**
UPDATE	Num 8	DATETIME20	*Earlier than TODAY()* **Last Update**
STATUS	I1	1=Active 0=inactive	*Default=1 (no missing)* **BreastWatch Status**

CONTACT (KEYSEN)

Variable name	Type and size	format	Comments/**label**

ENRICHID	I 4	F4.0	Autofill (key field) **Enrich ID**
LNAME	$20		**Last Name**
FNAME	$20		**First Name**
MI	$1		**MI**
DOB	Num 8	DATETIME20	*Between 1917 and 1981* **Date of Birth**
ADDRESS	$40		**Address**
CITY	$20		**City**
STATE	$2		**State**
ZIP	ZIP	$5	**Exactly 5 digits** **Zip Code**
HOMEPHONE	PHONE#	$15	*Exactly 10 digits* **Home Phone**
WORKPHONE	PHONE #	$15	*Exactly 10 digits* **Work Phone**
SSN	SSN	$11	**Exactly 9 digits** **SSN**
CELL	PHONE#	$15	*Exactly 10 digits* **Cell Phone**
EMAIL	$20	$20	**Email address**
DATE	Num 8	DATETIME20	*Earlier than TODAY()* **DATE**
UPDATE	Num 8	DATETIME20	*Earlier than TODAY()* **Last Update**
ENSTATUS	I1	1=Active 0=Withdrawn	Default=1. Change to 0 triggered by study withdrawal form **Enrich Status**

RANDOMIZATTION

Variable name	Type and size	format	Comments/**label**
ENRICHID	I 4	F4.0	Keyboard entry, lookup LNAME and print to screen for verification. Check ELIGIBILITY table: ELIGIBLE=1 and CONSENT=1 else error message to screen. **Enrich ID**
LDENSITY	I 2	F2.0	**Density Left**
RDENSITY	I 2	F2.0	**Density Right**
GAIL	R 4	F4.2	**Gail Score**
COLOR	I 1	1=RED 2=BLUE 3=YELLOW 4=ORANGE	Autofill based on stratification: Blocks of 10 Assign 2 colors to TX and 2 to PBO CLASSIFIED INFORMATION REQUIRES PASSWORD DENSITY=MAX(LDENSITY,RDENSITY) 4 Strata: DENSITY **[0-5] (5-10)]** GAIL **(0- 3.2](3.2- 20)** **Randomization Group**
DENSITY	R 2	F3.1	Computed and stored, appears on screen but no access from keyboard **MAX Density**
RANDDATE	Mmddyy10.	mmddyy10	Auto fill **Date Randomized**
EXAMDATE	Mmddyy10.	MMDDYY10.	Date density was measured **Date of Last Physical Exam**

VISIT 1 FLOW SHEET

Variable name	Type and size	format	Comments/**label**
ENRICHID	I 4	F4.0	Keyboard entry, lookup LNAME and print to screen for verification **Enrich ID**
VISITDATE	Mmddyy10.	Mmddyy10.	*Earlier than TODAY()* **Visit Date**
URINE	I1	1=Yes 0=No	**Urine Sample**
PREGTEST	I1	1=Positive 0=Negative	**PregTest Results**
LMP	Mmddyy10.	MMDDYY10.	*Earlier than TODAY()* **Last Menstrual Period**
CYCLE	I2	F2.0	**Menstrual Cycle** valid: x - xx ?
IRREGULAR	I1	1=Checked 0=Not Checked	**Irregular Cycle**
EDTA1	I1	F1.0	**EDTA Tube 1** valid: 0, 1
PAXGENE	I1	F1.0	**Paxgene Tubes** valid: 0, 1, 2
CPT	I1	F1.0	**CPT Tubes** valid 0, 1, 2, 3, 4
EDTA2	I1	F1.0	**EDTA Tube 2** valid: 0, 1
HEIGHTFT	R4	F1.0	**Height (Feet part)** valid:4 - 7?
HEIGHTIN	R4	F3.1	**Height (Inches part)** valid 0.0-11.9
WEIGHT	R4	F4.1	**Weight in Pounds** valid 90-400 ?
SYSTBP	I3	F3.0	**Systolic BP** valid xx-xxx ?
DIASBP	I3	F3.0	**Diastolic BP** valid xx- xxx ?
PULSE	I3	F3.0	**Pulse Rate** valid 50-100 ?
NIPPASP	I1	1=Yes 0=No	**Nipple Aspiration**
EXAMDATE	Mmddyy10.	Mmddyy10.	*Earlier than TODAY()* **Date of CBE**
VISIT2APP	Mmddyy10.	Mmddyy10.	**Appt Date V2**
V2APPTM	HH:MM	HH:MM	Integer fmt OK – will not be used in computations **Appt Time V2**
V2APPAMPM	$2	AM PM	**AMPM V2**
VISIT			Auto fill value= 1

Variable name	Type and size	format	Comments/label
ENRICHID	I 4	F4.0	*Enrich ID*
DATE	Mmddyy10.	Mmddyy10.	*Earlier than TODAY()* **Date of exam**
HEIGHTFT	R4	F1.0	**Height (Feet)** valid:4 - 7?
HEIGHTIN	R4	F3.1	**Height (Inches)** valid 0.0-11.9
WEIGHT	R4	F4.1	**Weight in Pounds** valid 90-400 ?
VISIT	I2	F2.0	*Visit number*
CBER	I 1	1=Normal 2=Abnormal, no change 3=Abnormal, new change 4=Abnormal, suspicious	**Clinical breast exam right**
CBEL	I 1	1=Normal 2=Abnormal, no change 3=Abnormal, new change 4=Abnormal, suspicious	*Clinical breast exam left*
RMAMMDATE	Mmddyy10.	Mmddyy10.	**Earlier than TODAY()** *Right mamm date*
RDENSITY	I 2	F2.0	**Density Right**
RRESULTS		1=Normal 2=Abnormal, no change 3=Abnormal, new change 4=Abnormal, suspicious	*Right mammogram results*
LMAMMDATE	Mmddyy10.	Mmddyy10.	*Earlier than TODAY()* **Left mamm date**
LDENSITY	I 2	F2.0	**Density Left**
LRESULTS	I 1	1=Normal 2=Abnormal, no change 3=Abnormal, new change 4=Abnormal, suspicious	**Left mammogram results**
RPATHDATE	Mmddyy10.	Mmddyy10.	*Earlier than TODAY()* **Right pathology date**
RPATHRES	I 2	1=No Diag Features 2=Fibroadenoma 3=Fibrocystic Change 4=Hyperplasia 5=Atypical Hyperplasia 6=LCIS 7=DCIS 8=Cancer 10=Other	If other, the written response is not entered . *We can generate a list of IDs, or names, where other was checked.* **Right pathology results**
LPATHDATE	Mmddyy10.	Mmddyy10.	*Earlier than TODAY()* **Left pathology date**
LPATHRES	I 1		**Left pathology results**
FOLLDATE	Mmddyy10.	Mmddyy10.	*Later than TODAY()* **Follow up appointment date**
FU1	I 1	1=Yes	**Needs follow up visit**
FU2	I 1	1=Yes	**Follow up with PCP**
FU3	I 1	1=Yes	**Send letter in 6 mo. (have no idea what this is for)**
FU4	I 1	1=Yes	**Patient needs mammogram**
FU5	I 1	1=Yes	**Patient does not need mammogram**

ENRICH DATA SOURCES

BREASTWATCH.MDB (lap top)

TABLE NAME	*Set up and programming*	*LINKING ELEMENTS*
KEYSBW	Brett	ROSEID unique subject id (key field) SSN DOB
BWQUEST	Brett	ROSEID unique subject id (key field) SSN DOB
BWQUESTUPD (we will just edit BWQUEST – question numbers correspond)	NA	ROSEID unique subject id SSN DOB
PHYSICAL EXAM (form and screen in place – may need a few modifcations)	JOHN	ROSEID unique subject id DATE date of exam A compound key
INACTIVE	NA	ROSEID unique subject id SSN DOB

ENRICH.MDB (lap top)

TABLE NAME	*Set up and programming*	*LINKING ELEMENTS*
KEYSEN	LORI (copy in from Brett's KEYSBW)	ENRICHID unique subject ID SSN DOB
ELIGIBILITY	LORI	ENRICHID unique subject id DOB
RANDOMIZATION	LORI	ENRICHID unique subject ID
PHYSICAL EXAM	JOHN	ENRICHID unique subject ID DATE **A compound key**
VISIT1FLOW	JOHN	ENRICHID unique subject ID
VISIT2FLOW	JOHN	ENRICHID unique subject ID
VISIT3FLOW	JOHN	ENRICHID unique subject ID
ENRICHQUEST (duplicate BWQUEST)	JOHN	ENRICHID unique subject ID
ADVERSE EVENTS	JOHN	ENRICHID unique subject ID
MEDSUPP	JOHN	ENRICHID unique subject ID
WITHDRAWAL	JOHN	ENRICHID unique subject ID
STUDYTABLETS	JOHN	ENRICHID unique subject ID RAND random number on tablet label **A compound key**
		ENRICHID unique subject ID

ENRICH LAB DATA (novell server)

FILE NAME		*LINKING ELEMENTS*
RANDOMIZATION	JOHN	RAND random number on tablet label
SELENIUM.XLS	ZHU	ENRICHID unique subject ID ACCESSION
CYTOLOGY	JOHN	ENRICHID unique subject ID ACCESSION
OHdG	AL	ENRICHID unique subject ID ACCESSION
EPG	AL	ENRICHID unique subject ID ACCESSION